EVALUATION OF EFFECT OF YOGA THERAPY ON OXIDATIVE STRESS STATUS IN TYPE 2 DIABETIC PATIENTS WITH HYPERTENSION

A dissertation submitted to

THE TAMILNADU DR.M.G.R MEDICAL UNIVERSITY

CHENNAI-600032

in partial fulfillment of the requirements for the award of the degree of

MASTER OF PHARMACY
IN
PHARMACOLOGY

Submitted by
Registration number: 261426062

INSTITUTE OF PHARMACOLOGY
MADRAS MEDICAL COLLEGE
CHENNAI- 600003
APRIL 2016

CERTIFICATE

This is to certify that the dissertation entitled "**EVALUATION OF EFFECT OF YOGA THERAPY ON OXIDATIVE STRESS STATUS IN TYPE 2 DIABETIC PATIENTS WITH HYPERTENSION"**, submitted by the **Register number: 261426062** in partial fulfillment of the requirements for the award of Master of Pharmacy in Pharmacology by The Tamilnadu Dr. M.G.R Medical University, Chennai is a bonafide record work carried out by him under the guidance of **Dr. N. Jayshree, M.Pharm, Ph.D.,** in Institute of Pharmacology, Madras Medical College, Chennai during the academic year 2015-2016.

The Dean,
Madras Medical College,
Chennai- 600003.

Place: Chennai - 3

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Dr. B.Vasanthi , M.D,D.O.,
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CONTENTS

ABBREVIATIONS

S.NO	TERMS	ABBREVATIONS
1	BP	Blood pressure
2	BMI	Body mass index
2	BMR	Basal metabolic rate
4	GSH	Glutathione
5	HNE	4 hydroxy nonenol
6	MDA	Malondialdehyde
7	NADPH	Nicotinamide adenine dinucleotide phosphate
8	NIDDM	Non insulin dependent diabetes mellitus
9	PR	Peripheral resistance
10	ROS	Reactive oxygen species
11	SOD	Super oxide dismutase
13	TBA	Thiobarbituric acid
14	TBARS	Thiobarbituric acid reactive substance

INTRODUCTION

Stress is a reaction to a stimulus that disturbs our physical or mental equilibrium. In other words, it is an omnipresent part of life. A stressful event can trigger the "fight-or-flight" response, causing hormones such as adrenaline and cortisol to surge through the body. A little bit of stress, known as "acute stress," can be exciting—it keeps us active and alert. But long-term, or "chronic stress," can have detrimental effects on health. It may not be possible to control the stressors in the world but it is possible to alter one's reaction to them.

Oxidative stress is defined as a state in which oxidation exceeds the anti oxidant defence systems in the body, secondary to a loss of the balance between them. Oxidative stress is well known to be involved in the pathogenesis of life style diseases including atherosclerosis, hypertension, diabetes mellitus, ischemic heart diseases and malignancies. If the oxidation exceeds antioxidant systems, the metabolism of oxygen as well as the generation of the Reactive oxygen species (ROS) are increased. [1]

Reactive oxygen species:

Reactive oxygen species (ROS) are chemically reactive molecules containing oxygen. Examples include peroxides**,** superoxide**,** hydroxyl radical and singlet oxygen. ROS are formed as a natural byproduct of the normal metabolism of oxygen and have important roles in cell signalling and homeostasis. However, during times of environmental stress, ROS levels can increase dramatically. This may result in significant damage to cell structures. [2]

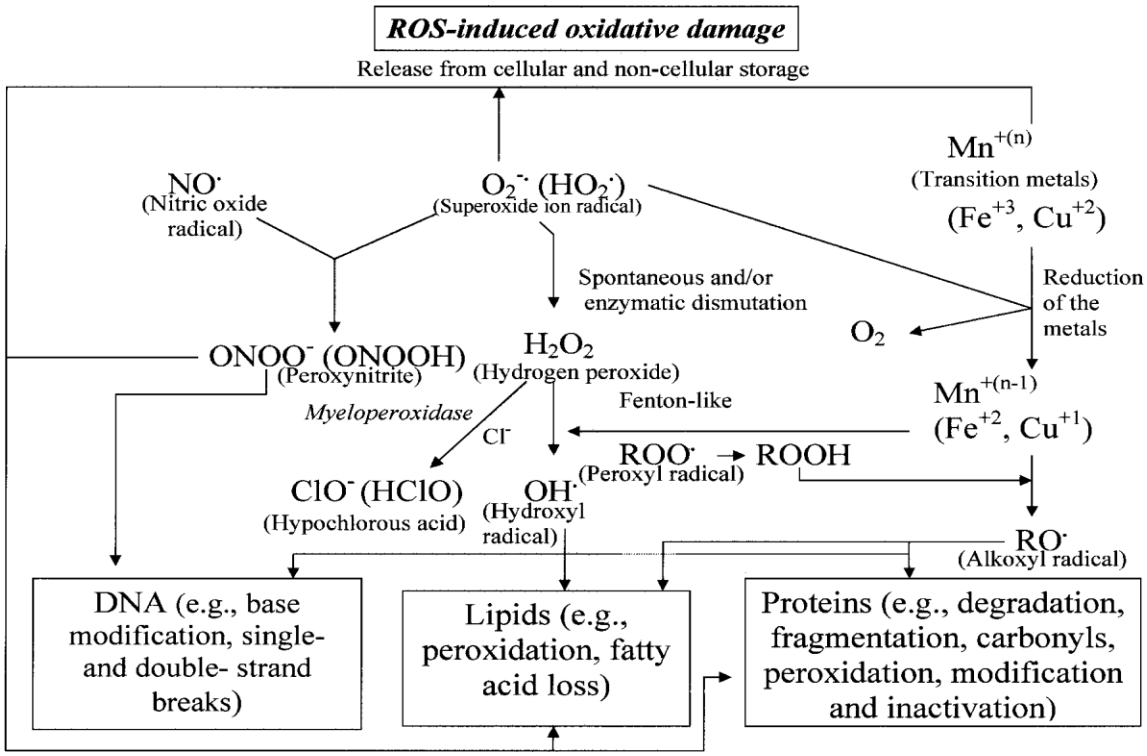


***Fig: 1** ROS – induced oxidative damage.*

In general, harmful effects of reactive oxygen species on the cell are

1. DNA damage

2. Oxidation of polyunsaturated fatty acids in lipids (lipid peroxidation).

3. Oxidation of amino acids in proteins

4. Oxidative deactivation of specific enzymes by oxidation of co-factors.

Involvement of Reactive oxygen species in Lipid peroxidation:

Lipid peroxidation refers to the oxidative degradation of lipids. It is the process in which free radicals "steal" electrons from the lipids in cell membranes, resulting in cell damage. The end products of lipid peroxidation are reactive aldehydes, such as Malondialdehyde (MDA) and 4-hydroxynonenal (HNE). These are considered as bioactive markers of lipid peroxidation.

The quantification of the end-products of lipid peroxidation, to be specific MDA, is done by TBARS assay (thiobarbituric acid reactive substances assay). This is a reliable and inexpensive method for estimation of Malondialdehyde (MDA). The lipids in the cell membranes are highly susceptible to peroxidative damage and are broken down into number of small units to form malondialdehyde. This reacts with thiobarbituric acid (TBA) to form Thiobarbituric acid reacting substance (TBARS) which has a pink color with absorption maxima at 532nm.

Pathogenesis of Reactive oxygen species in case of the type 2 diabetes:

Type 2 diabetes is the most prevalent and serious metabolic disease all over the world. It is characterized by pancreatic cell dysfunction and insulin resistance leading to chronic hyperglycemia and subsequent augmentation of reactive oxygen species (ROS) levels. These further deteriorate cell function and increase insulin resistance which leads to the aggravation of type 2 diabetes. Therefore, ROS play an important role in the development of type 2 diabetes. [3]

Pathogenesis of Reactive oxygen species in case of Hypertension:

Hypertension is also associated with an elevation of ROS and frequently associated with an impairment of endogenous antioxidant mechanisms. Experimental manipulation of the redox state *in vivo* shows that ROS can be a cause of hypertension. During the development of the disease, ROS are generated by endogenous sources, notably the NADPH oxidase enzyme family and uncoupled nitric oxide synthase, due to a mutual reinforcement between ROS and humoral factors. The ROS affect multiple tissues, either directly or through nitric oxide depletion. In the vasculature, they induce contraction and endothelial dysfunction. In blood vessels and myocardium, they cause hypertrophic

remodeling. In the kidneys, ROS promote salt reabsorption, decreases glomerular filtration and leads to tissue damage. Finally, they also increase efferent sympathetic activity from the central nervous system. [3]

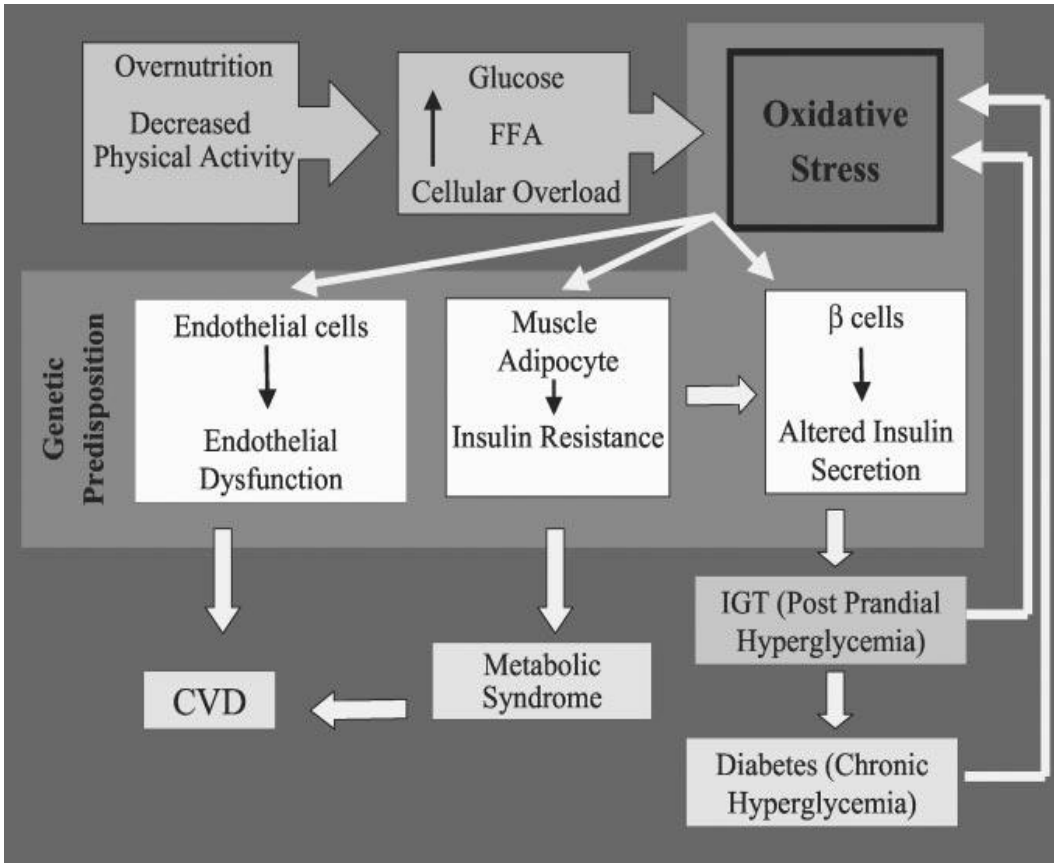


Fig: 2 *The mechanisms through which the oxidative stress is involved in the pathogenesis of Type 2 diabetes and in hypertension*

How yoga helps in Diabetes and Hypertension:

Yoga is a physical, mental and spiritual practice or discipline which originated in India. Yoga is the most favourable method to connect to the nature by balancing the mind-body connection. It is a type of exercise which is performed through the balanced

body along with control over diet, breathing and physical postures. It is associated with the meditation of body and mind through the relaxation of body. It is very useful to control the mind and body as well as getting proper health of body and mind by reducing stress and anxiety.[4]

Yoga can be practiced by anyone as an exercise on a daily basis to fulfill the need of the very active and demanding life especially teenagers and adults. Many studies have tried to determine the effectiveness of yoga as a complementary intervention for cancer, schizophrenia, asthma and heart disease. Yoga has been found to control both diabetes and hypertension in efficient manner by minimizing the generation of ROS and thereby preventing or arresting the progress of the disease condition. [5]

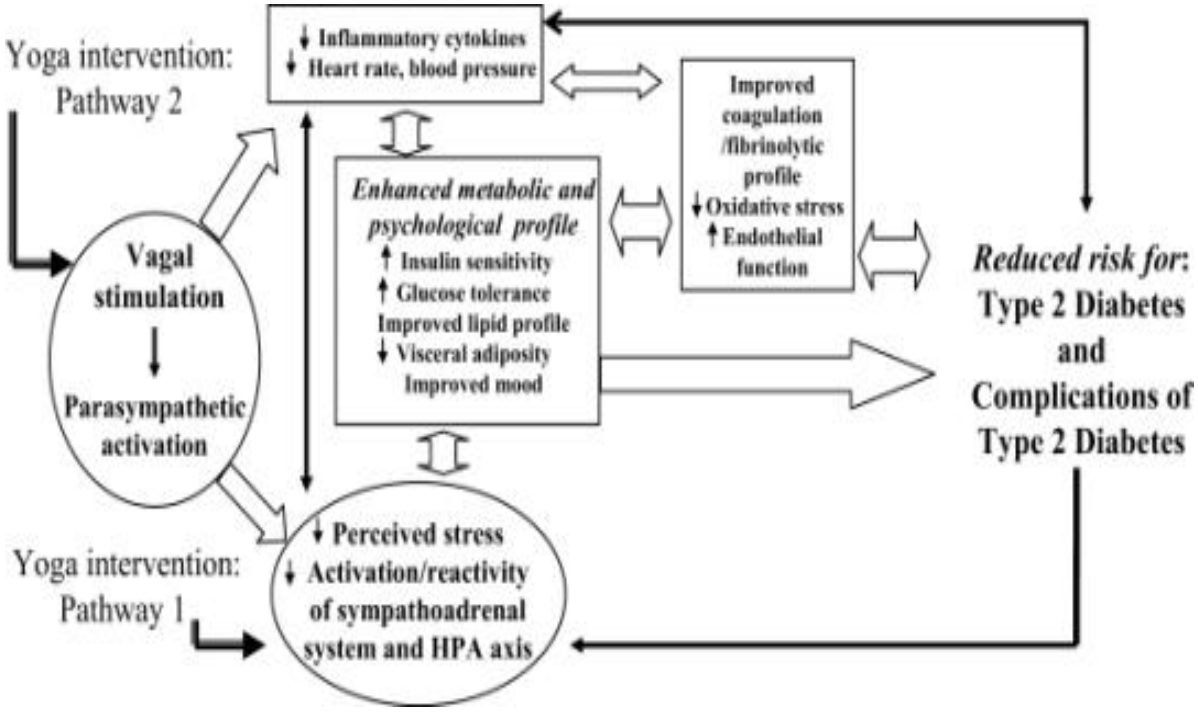


Fig: 3 *Physiological changes produced by the yoga for reducing the risk and complications of type 2 diabetes.*

REVIEW OF LITERATURE

Shreelaxmi V. Hegde[1] *et al.,* have in their study, reported that in comparison with standard care alone, yoga resulted in significant reduction in BMI, glycemic control, and malondialdehyde levels as well as an increase in glutathione and vitamin C levels making Yoga an effective therapy in reducing oxidative stress in type 2 diabetes. In addition to standard care, yoga helps to reduce BMI and improve glycemic control over type 2 diabetic patients.

Rani K Beena and E Sreekumaran[4] in their study have proved that there was a significant difference in glucose, HbA_{1c}, lipids, cortisol, ferritin, MDA levels and significant increase in catalase activity after yogic practice. Yoga may improve risk profiles induced by stress in geriatric patients with type 2 diabetes and may have promise for the prevention or delay in diabetes complications.

Satish G Patil and Gopal B Dhanakshirur[5] have reported that yoga practice for hypertension up to three months has significantly reduced serum MDA level and enhanced antioxidants levels of SOD activity, GSH and vitamin C. These findings suggest that yoga is an effective means to reduce oxidative stress and to improve antioxidant defense in elderly hypertensive individuals.

Lorenzo A Gordon[6] *et al.,* have demonstrated the efficacy of Hatha yoga exercise on fasting blood glucose, lipid profile, oxidative stress markers and antioxidant status in patients with type 2 diabetes and suggest that Hatha yoga exercise and conventional PT

exercise may have therapeutic, preventative and protective effects on diabetes mellitus by decreasing oxidative stress and improving antioxidant status.

Sinha S[7] *et al.*, have suggested that regular practice of yoga can maintain or improve antioxidant levels of the body. The reduced glutathione level increased significantly in the yoga group after completion of training. Glutathione reductase activity increased significantly in the control group. Total antioxidant systems increased significantly in the yoga group and decreased significantly in the control group. The clinical relevance is that yoga practice can be used to maintain the antioxidant defense system under stressful conditions of training as observed in the case of soldiers and athletes.

P. Martin-Gallan[13] have reported that overall increase in lipid and protein oxidative damage biomarkers that precedes or accompanies the early stages of diabetes- related development of complications points to oxidative stress processes as potential pathogenic mechanisms, precursors of microvascular alterations in diabetes. Moreover, they showed that hyperlipidaemia caused by diabetes-associated loss of optimal regulation of lipid metabolism implies greater susceptibility to oxidation that would lead and significantly contribute to the extent of lipid and protein oxidation, thereby supporting the concept of glucose toxicity and lipotoxicity being interrelated. Therefore, concerted efforts should be made to reduce oxidative lipaemia and oxidant stress in an attempt to potentially delay the development and/or progression of early microvascular complications. Consequently, tight lipid and glycometabolic control may have therapeutic potential by diminishing oxidative tissue damaging effects of hyperglycaemia.

Senthil Raj Thangasami[18] ***et al.,*** suggest that Yoga may be an attractive alternative to traditional aerobic exercises and strength training program, as it requires only a little space and needs no equipment and literally devoid of side effects, mainly focusing on relaxation of mind and body. It provides a less strenuous and more pleasurable exercise experience to an individual. Yoga can help the person feel better, both improving the physical fitness and elevating the mood. Further it can alleviate stress. So, Yoga can be considered as a good alternate for exercise therapy.

Kyeongra Yang and Lisa M. Bernardo[19] have in their preliminary study indicated that a yoga program would be a possible risk reduction option for adults at high risk for type 2 diabetes. In addition, yoga holds promise as an approach to reducing cardiometabolic risk factors and increasing exercise self-efficacy for this group.

Nisha Shantakumari and Shiefa Sequeira[20] have concluded that some of the chosen yogic practices are very effective in correcting the hypertension seen in a diabetic patient.

Deepa T[21] ***et al.,*** have suggested that the yoga technique can be used as adjunctive therapy with drug therapy for patients with mild and moderate hypertension. Yoganidra, a kind of meditation and muscle relaxation technique can be used to treat mild hypertension before beginning of drug therapy. It can be practiced as one of lifestyle modification therapy in pre hypertensives and those with strong family history.

M. Sharma and M. Meena[22] have in their study concluded that yogic practices combined with anti-hypertensive drugs were found to be effective in reducing BP & PR in resting condition and during stimulus induced conditions as well in mild to moderate

hypertension. It reduced the requirement of the dose of antihypertensive drugs in majority of the hypertensive patients.

Malhotra V and Singh S[23] have reported that Yogasanas in mild to moderate NIDDM cases, used in addition to normal medical therapy, would give benefit to the patient and improve the status of Diabetics in terms of use of less medicine, improvement of physical well being, improvement in mental alertness and activity and leading a complication free life. Consequently, it is suggested that *Yoga asanas* and *pranayamas* may be used as an adjunct therapy to reduce Diabetes Mellitus. In overweight NIDDM patients on *Yoga asanas*, insulin levels were brought back to normal from a very high basal level.

Yang K[25] showed that yoga interventions are generally effective in reducing body weight, blood pressure, glucose level and high cholesterol.

Sharma R, **Gupta N**, **Bijlani RL**[27] have found that change in eating habits, reducing the body weight, cessation of smoking habits, exercise including yoga have a key role in the prevention of type 2 diabetic conditions.

Aljasir B, **Bryson M**, **Al Shehri B**[31] have measured the "subject well being inventory" scores of patient with diabetes. These observation showed that these was an improvement in the subject within a period of 10 days.

Chaya MS, **Ramakrishnan G**, **Shastry S**[32] showed that long term yoga practice (for 1 year or more) is associated with increased insulin sensitivity and attenuates the negative relationship between body weight or waist circumference and insulin sensitivity.

AIM AND OBJECTIVES

PRIMARY AIM:

From the literature review, it is clear that practice of yoga has been able to reduce the oxidative stress levels in diabetic and hypertensive patients seperately. No scientific study has so far been carried out to evaluate the effect of yoga practice on oxidative stress status of the patients who are diabetic and also hypertensive.

The primary aim of the study is to investigate the effect of yoga on oxidative stress in type 2 diabetic patients with hypertension.

SECONDARY AIM:

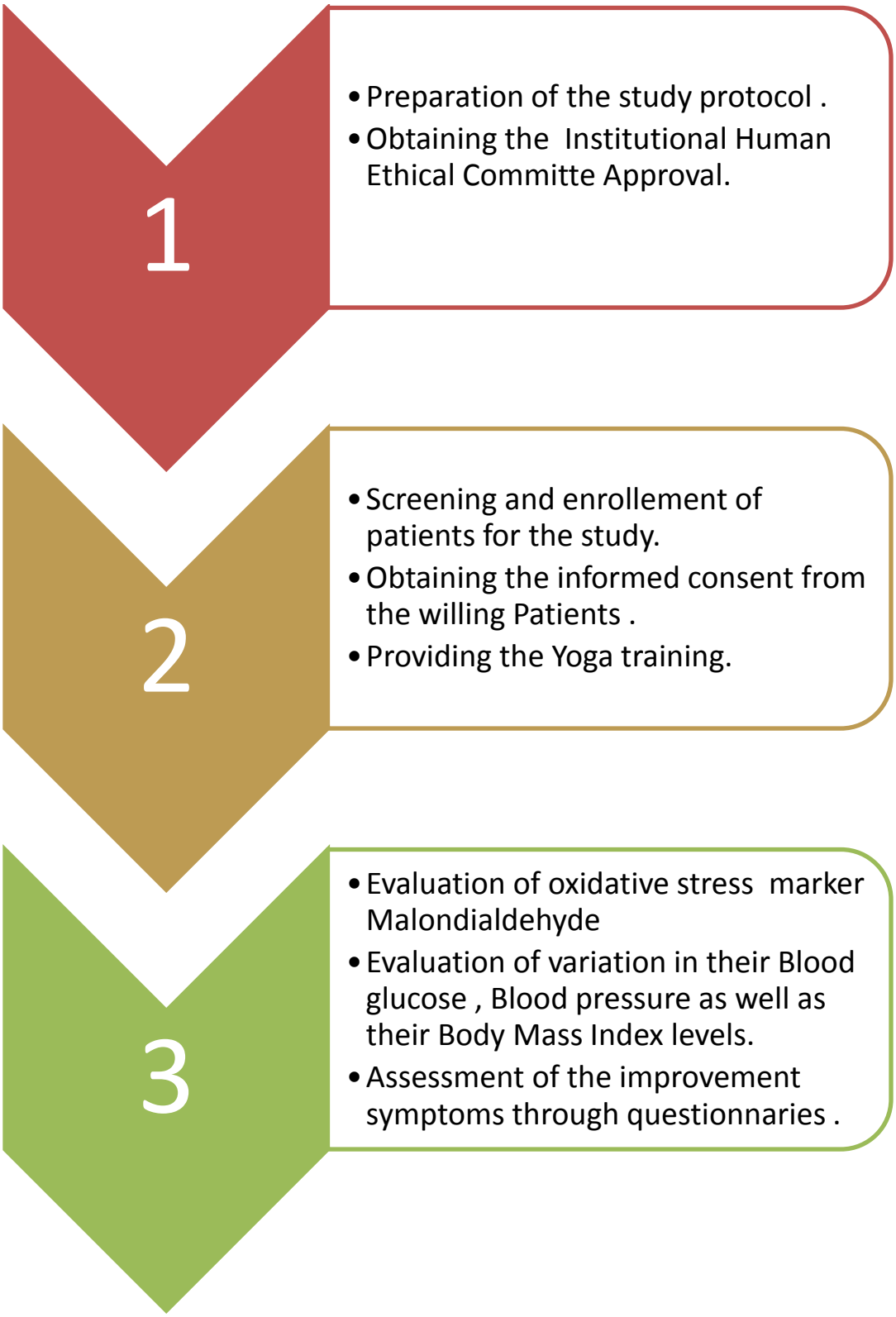
If the study is able to prove that there is a decrease in the oxidative stress markers and reduction in glucose and blood pressure levels in patients who are diabetic and also hypertensive when on intervention with yogasanas, it can then help us to extrapolate the findings to reduce the doses of the anti diabetic and anti hypertensive drugs thereby reducing their side effects.

OBJECTIVES:

1. To evaluate the effects of 45 days of integrated approach of yoga therapy (IAYT) on lipid peroxidation biomarkers in type 2 diabetic patient with hypertension.

2. To assess and compare the changes of blood glucose level (both fasting and post prandial), Blood pressure and BMI in type 2 Diabetic Patient with hypertension before & after 45 days of Yoga therapy.

PLAN OF WORK


1
• Preparation of the study protocol .
• Obtaining the Institutional Human Ethical Committe Approval.
2
• Screening and enrollement of patients for the study.
• Obtaining the informed consent from the willing Patients .
• Providing the Yoga training.
3
• Evaluation of oxidative stress marker Malondialdehyde
• Evaluation of variation in their Blood glucose , Blood pressure as well as their Body Mass Index levels.
• Assessment of the improvement symptoms through questionnaries .

METHODOLOGY

STUDY DESIGN : Interventional, Prospective, Open label.

STUDY POPULATION : 30 patients with Type 2 Diabetes along with Hypertension.

STUDY CENTER : Institute of Diabetology, Madras Medical College & Rajiv Gandhi Government General Hospital, Chennai.

STUDY PERIOD : October 2015 – February 2016.

SAMPLE SIZE : 30 patients.

STUDY DURATION : 45 days.

Inclusion Criteria:

1. Patients with Hypertension diagnosed with Type 2 Diabetes within five years.
2. Patients aged 40- 60 years.
3. Both sexes.
4. Patients who are willing to participate in study.

Exclusion Criteria:

1. Pregnant and lactating women.
2. Patients who are physically handicapped and mentally ill.
3. Patients with any complications of diabetes (retinopathy and nephropathy).
4. Patients who were practicing yoga for a month or more.

5. Patients with neoplastic, hepatic, thyroid dysfunctions, respiratory and any cardiovascular disorder or other medical illness (i.e. respiratory and heart failure and renal disease)

6. Patients doing other physical activities. (Swimming, aerobic exercises, etc)

STUDY PROCEDURE:

The study was conducted after obtaining the approval from the Institutional Ethics Committee, Madras Medical College, Chennai.

Enrolment of patients:

Patients diagnosed with Type 2 Diabetes Mellitus as well as hypertension undergoing treatment as outpatients in the Institute of Diabetology, Madras Medical College & Government General Hospital were selected for the study. Patients who fulfilled the inclusion criteria were explained about the study purpose and procedures. Informed consent was obtained from the patients who were willing to participate in the study in the prescribed format in regional language. If the patient was illiterate, left thumb impression in the presence of an impartial witness was taken. The demographic details of the patients were obtained and recorded. History of the patients was taken. The general & systemic examinations were carried out.

Following assessment was done at the baseline and at the end of 45 days on the patient,

Primary assessment:

1. 3ml of the blood sample was drawn from the median cubital vein and transferred to EDTA coated tubes which was then centrifuged at 4°C to separate the plasma. Separated plasma was stored at -80°C for the later estimation of the MDA levels.

Secondary assessment:

1. Body height and weight was measured to determine the body mass index.

   BMI= Weight (kg) / Height^2(m^2)

2. Using the glucometer, the fasting blood glucose levels was measured
3. Using the sphygmomanometer, systolic and diastolic blood pressure was measured.
4. The assessment of improvement of symptoms was done using the questionnaire given in the table 1.

Table 1: *Diabetic symptom check list questionnaire.*

S.NO	QUESTIONS	NOT AT ALL	A LITTLE	MODERATELY	VERY	EXTREMELY
1	Lack of energy					
2	Aching calves when walking					
3	Numbness in feet					
4	Sense of fatigue					
5	Very thirsty					
6	Palpitations or pounding in the heart region					
7	Dry mouth					
8	Irritability just before the meal					
9	Frequent need to empty your urine					

INTERVENTION WITH YOGA SCHEDULE:

The following yogasana schedule was designed after consultation with yoga specialists and this was a perfect combination of asanas and breathing exercises.

All the patients were trained in order to the follow this yoga schedule for 45 days.

Om Chanting (9 Times)	10 min
Followed by Breath Awareness	3 min
Vajrasan Shashankasan Ushtrasan Paschimottasan Chakki Chalanasan Ardha Matsyasan Bhujangasan Ardha Matsyendrasan Meru Vakrasan Shavasan	10 mins (selective according to the Patient condition)
Nadi Shuddhi Pranayam (9 Rounds)	2 min
Abdominal Breathing – Sitting	5 min

The patients were trained to perform these asanas. They were recommended to practice these asanas twice a day. They were also handed over a booklet regarding the same. If they found any difficulty in performing those asanas or if they felt any pain or injury while performing any asana, modification form of that particular asana was made

by the yoga specialist. Patients practicing yoga were asked to report once in 15 days to ensure that they were practicing the yogasana schedule regularly and they had no difficulty in performing the asanas.

Measurement of MDA by colorimetric method:

TBARS assay kit was purchased from the Caymen Chemicals, USA. This test kit contains 2 ml (500µM) of Malondialdehyde standard, standard sodium dodecyl solution(SDS), TBA acetic acid, TBA sodium hydroxide and 2 g of Thio barbituric acid.

1. Preparation of colour reagent:

530 mg of TBA was weighed and transferred to a 150 ml beaker containing 50ml of diluted TBA Acetic acid solution. 50 ml of diluted TBA sodium hydroxide was added and mixed until the TBA is completely dissolved. The solution is stable for 24 hours. This volume is sufficient for carrying out the assay for 24 sample.

2. Sample preparation:

Blood was collected and transferred to EDTA coated tubes. It was centrifuged at 2000 rpm for 10 minutes at 4°C. The top yellow plasma layer was pipette off without disturbing the white buffy layer. The plasma was stored on ice and then transferred to a deep freezer at -80°C. The plasma sample is expected to be stable for one month when stored at -80°C. Plasma does not need to be diluted before assaying.

3. MDA standard preparation:

250 µl of the MDA standard was diluted with 750 µl of water to obtain a stock solution of 125µM. Further dilution of this stock solution was made as per the scheme given below into 8 tubes named A to H as described in table 2,

Table 2: *Dilution procedure for the colourimetric standards.*

Tube	MDA(µl)	Water(µl)	MDA concentration(µM)
A	0	1000	0
B	5	995	0.625
C	10	990	1.25
D	20	980	2.5
E	40	960	5
F	80	920	10
G	200	800	25
H	400	60	50

Procedure for performing the assay:

1. Vial caps were labeled with standard number or sample identification number.
2. 100µl of sample or standard was added to appropriately labeled 5 ml vial.
3. 100 µl of SDS solution was added to vial and swirl to mix.

4. 4ml of the color reagent was added forcefully down side of each vial.
5. The Vials were positioned upright during boiling by using holders.
6. The vials were boiled for one hour in vigorously boiling water.
7. After one hour, vials were removed immediately and placed in ice bath to stop the reaction. They are Incubated on ice for 10 minutes.
8. After 10 minutes, vials were centrifuged for 10 minutes at 2000 rpm at 4°C. (Vials may appear clear or cloudy. Cloudiness, if present, cleared upon warming the drugs to the room temperature)
9. Vials were stabilized at room temperature for 30 minutes.
10. 3ml from each vial was loaded to cuvette .
11. Absorbance was read at 532 nm using UV spectrophotometer.
12. From the standard MDA, a calibration curve was plotted. By means of interpolation, the concentration of the test samples was detected.

Withdrawal from the study:

During the study period, the subjects were allotted to withdraw from the study at any point, if they so desired.

Statistical Analysis Plan:

Using one way ANOVA method .

RESULTS AND DISSCUSSION

At the end of 45 days, many patients reported that they were not able to practice the yoga regularly due to their time, social, economical and situational constraints. Hence to assess the results, grouping of the patients was done on the basis of their regularity of following the yogasana schedule.

Based on the adherence of the patients towards the yoga intervention, patients were categorized in 3 groups as given below,

Table 3: *Categories of the patient based on their adherence towards the yoga intervention.*

GROUP	Frequency of performing Yoga	Number of Patients
Group 1	Practiced more than 10 sessions per week	6
Group 2	Practiced 6-9 sessions per week	13
Group 3	Practiced not more than 6 sessions per week	5

1. MALONDIALDEHYDE LEVELS:

The Malondialdehyde levels before and after 45 days of yoga intervention are given in table 4 and in figure 4 .

Table 4 :

Group	Malondialdehyde Levels (µMoles/litre)	
	Before(0 day)	After(45th day)
1	65±18.19	34.5±9.37**
2	65.61±14.73	46.15±15.74**
3	63.2±14.78	65.4±21.37

The values are expressed as (Mean ± S.D)

**p <0.05, **p<0.01, ***p<0.001*

Yoga practice and meditation techniques have the tendency to reduce the BMR there by automatically diminishing the production and increased elimination of free radicals from the body[2]. This is confirmed by assessing the lipid peroxidation metabolite MDA levels which shows the significant reduction up to $p<0.01$ in group 1 patients, in group 2 Patients and $P<0.5$ in group3 patients respectively.

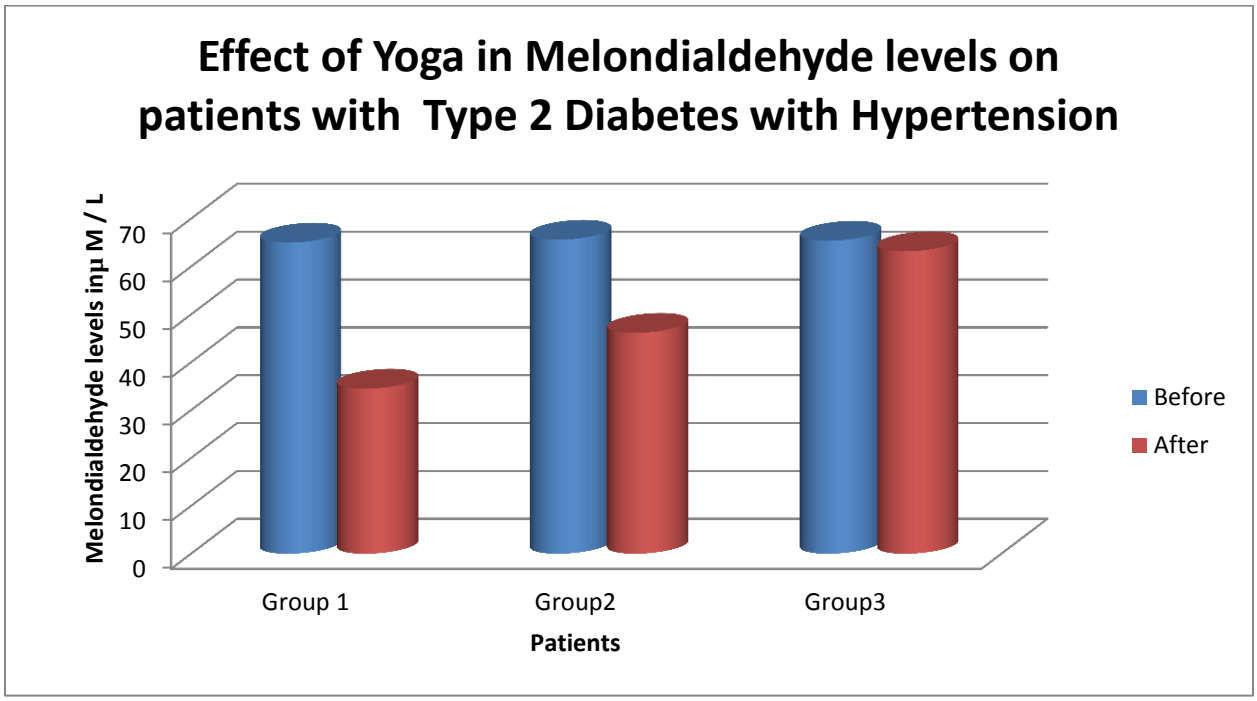


Fig: 4

2. BODY MASS INDEX :

The Body mass Index before and after 45 days of yoga intervention are given in table 5 and in figure 5.

Table 5:

Group	Body Mass Index (BMI)	
	Before(0 day)	After (45th day)
1	23.93±2.36	23.19±2.46
2	21.12±6.60	20.87±6.59
3	23.76±4.35	23.64±3.30

The values are expressed as (Mean ± S.D)

**p <0.05, **p<0.01, ***p<0.001*

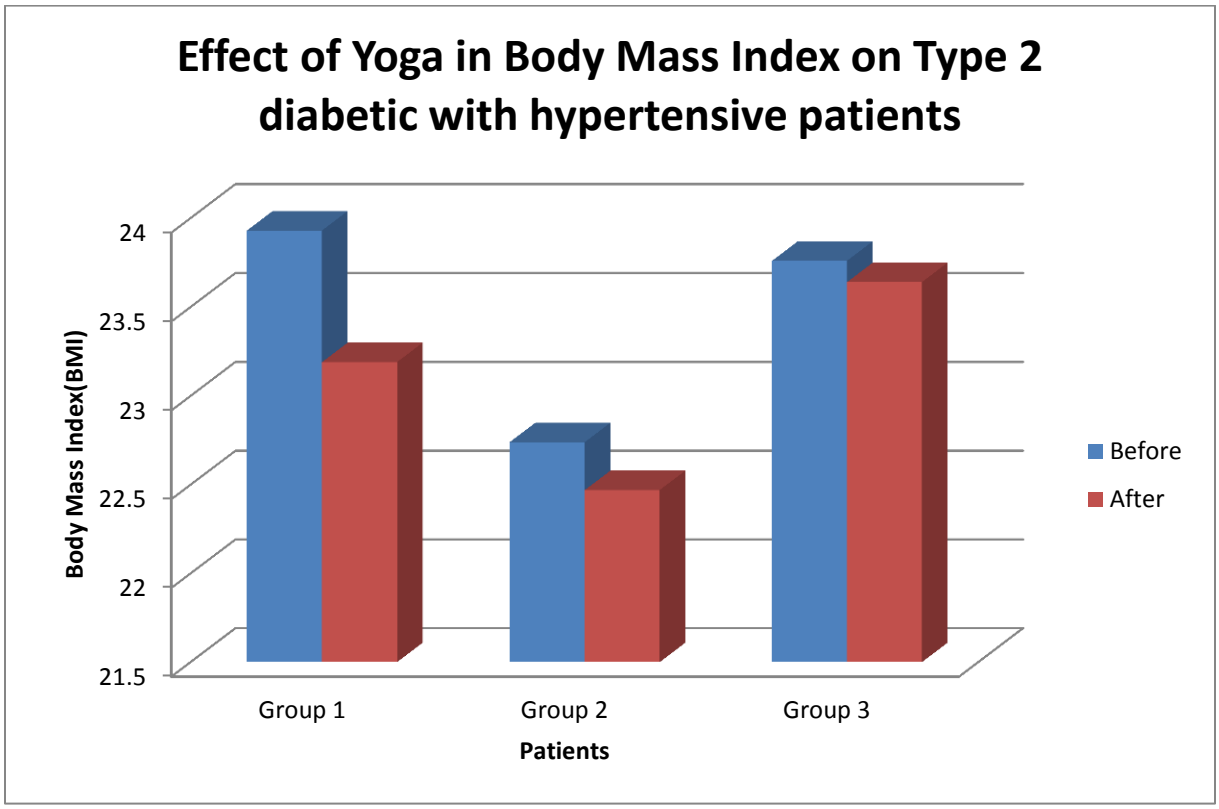


Fig: 5

In this study the effect of yoga on decreasing the BMI was not found to be statistically significant, but many studies have shown the effective control over the BMI in yoga patients. The patients could not be kept under direct supervision for the entire period of the study. Dietary data were also not recorded regularly. Long term study may need to show the variations in the body mass index of the patient.

3. BLOOD GLUCOSE LEVELS:

The bloood glucose levels before and after 45 days of yoga intervention are given in table 6 and in figure 6.

Table 6:

Group	Blood Glucose Levels (mg/dl)	
	Before(0day)	After(45th day)
1	370.83±143	143±63.17**
2	213.66±130.25	130.25±53.95**
3	207±146.4	155.6±48*

The values are expressed as (Mean ± S.D)

**p <0.05, **p<0.01, ***p<0.001*

In group 1 and 2, p value is more significant (P<0.01) when compared to the group 3 (P<0.05). This demonstrates that the Yoga acts by providing significant increase in insulin sensitivity, decrease in insulin resistance and a significant rise in the number of insulin receptors by following yogic-intervention. These could explain significant decline in the fasting blood glucose levels values of the Patients after yogic practice.

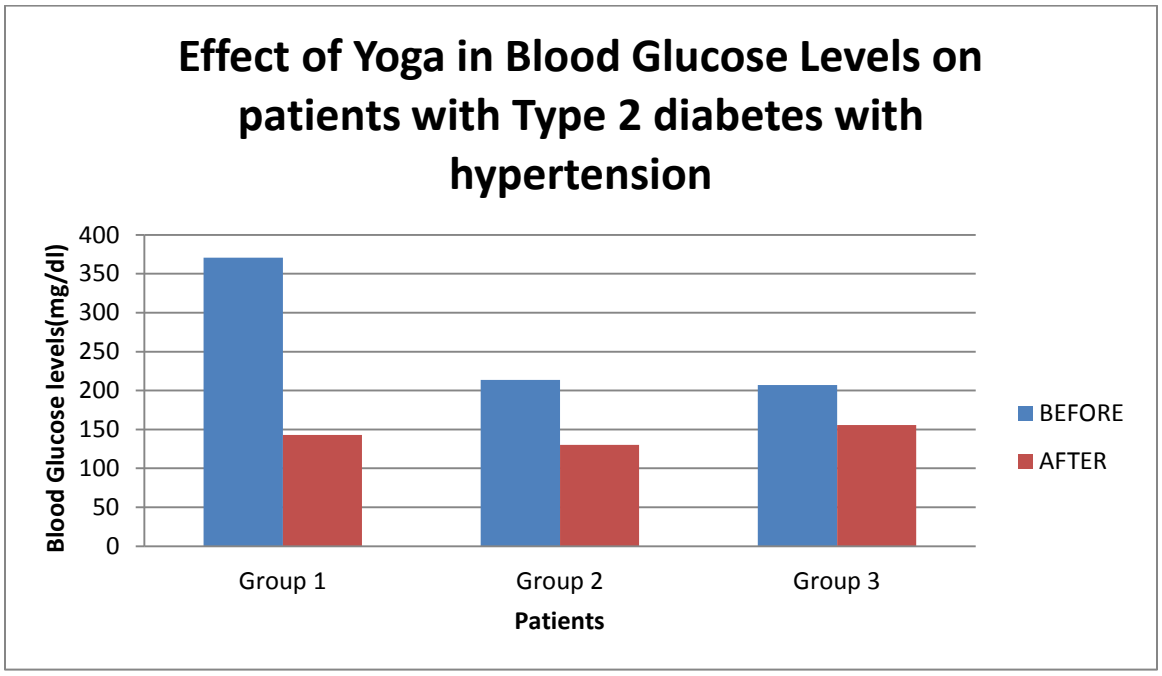


Fig: 6

4. SYSTOLIC BLOOD PRESSURE:

The systolic blood pressure before and after 45 days of yoga intervention are given in table 7 and in figure7.

Table 7:

Group	Systolic Blood Pressure Levels (mm/Hg)	
	Before(0day)	After(45th day)
1	191.33±14.5	150.66±21.63**
2	199.38±32.69	179.07±35.97*
3	183.6±34.33	179±31.57

The values are expressed as (Mean ± S.D)

**p <0.05, **p<0.01, ***p<0.001*

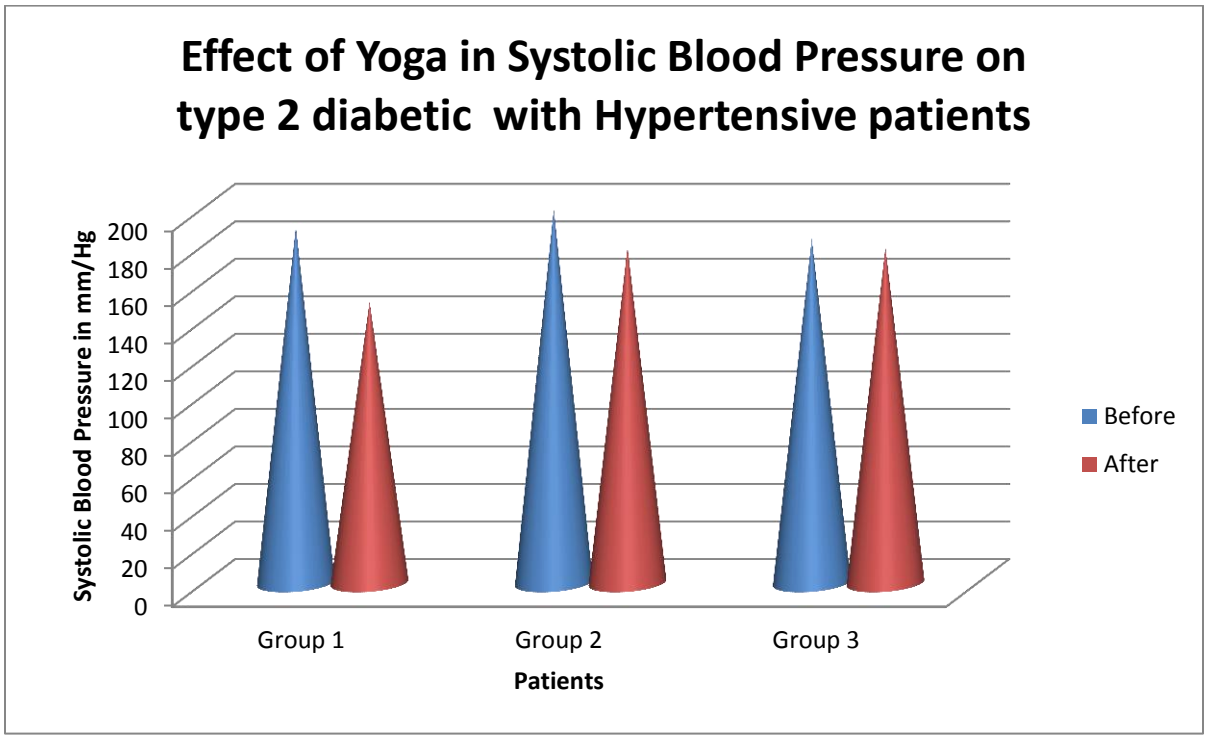


Fig: 7

P value is statistically significant in first two groups even in that first group ($p<0.01$) shows more significant value when comparing to group 2 ($p<0.05$) but group 3 patient does not show any statistically difference which obviously demonstrates the regularity of the yoga practice is much more essential one in case of maintaining the systolic blood pressure[3].

5. DIASTOLIC BLOOD PRESSURE :

The Diastolic blood pressure before and after 45 days of yoga intervention are given in table 8 and in figure 8.

Table 8:

Group	Diastolic Blood Pressure Levels (mm/Hg)	
	Before(0 day)	**After(45th day)**
1	150.33±17.99	114.66±18.40**
2	154±23.81	136.61±31.83*
3	148±32.71	147.2±36.70

The values are expressed as (Mean ± S.D)

**p <0.05, **p<0.01, ***p<0.001*

P value is statistically significant in first two groups even in that first group ($p<0.01$) shows more significant value when comparing to group 2 ($p<0.1$) but group 3 patient does not show any statistically difference which obviously demonstrates the regularity of the yoga practice is much more essential one in case of maintaining the systolic blood pressure.

In this study, there was a significant reduction in levels of both systolic and diastolic blood pressure after 45 days of yoga practice due to Yogasanas increase baroreceptors sensitivity and hence effective control over blood pressure[2].

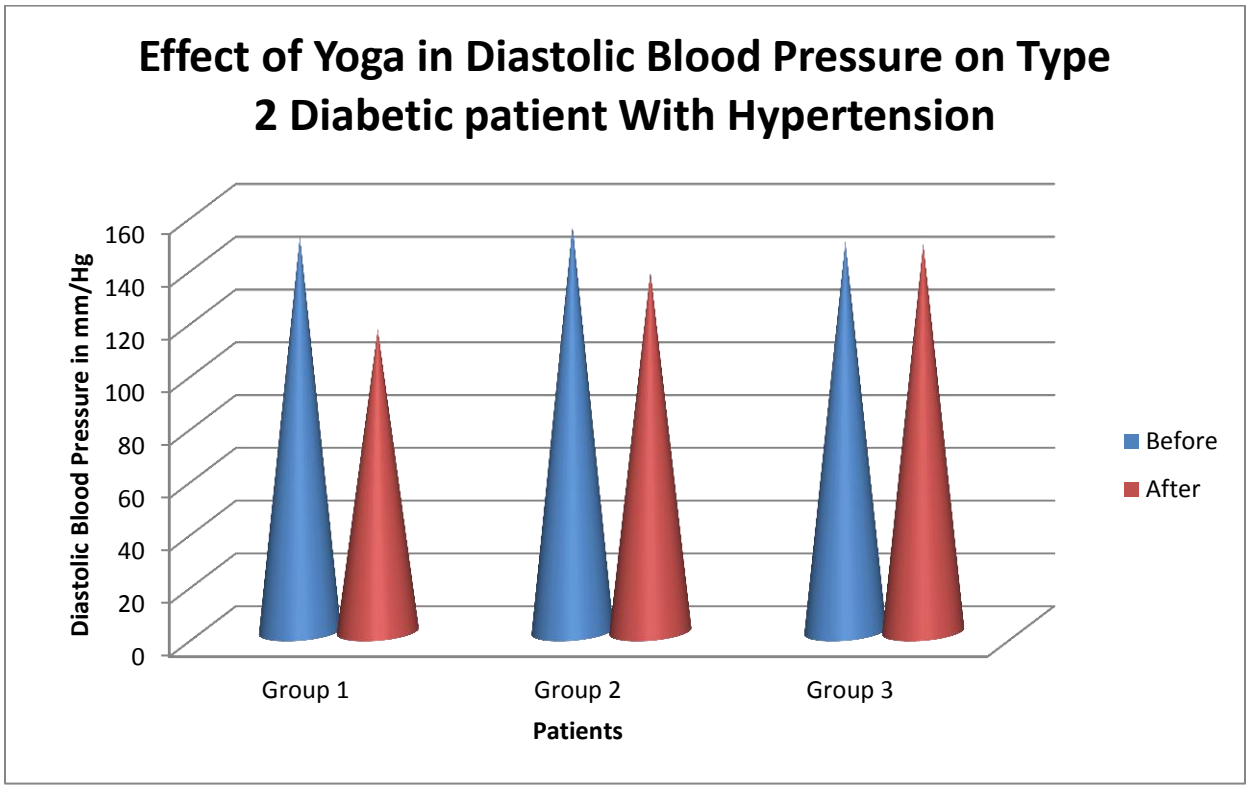

Effect of Yoga in Diastolic Blood Pressure on Type 2 Diabetic patient With Hypertension
Diastolic Blood Pressure in mm/Hg
160
140
120
100
80
60
40
20
0
Group 1
Group 2
Group 3
Patients
Before
After

Fig: 8

5. DIABETIC SYMPTOM CHECK LIST BEFORE AND AFTER THE 45 DAYS OF YOGA INTERVENTION:

The questionnaires focused mainly on the following symptoms:

A. Energy levels

B. Urination frequency

C. Aching in calves

D. Intensity of the dry mouth

E. Thirst frequency

F. Irritatability before the meal

G. Numbness or loss of sensation on the feet

H. Palpitations in the heart

I. Sense of fatigue.

These parameters as experienced by the patients before and after the yoga intervention are given in the tables 9-17 and figures 9-17.

A. Energy levels:

Distribution and Variation in energy levels of the patient before and after the 45 days of Yoga Intervention is shown in table 9 and in figure 9.

Table 9:

Assessment Rankings for Energy levels	Number of Patietnts	
	Before(0 day)	After(45th day)
1(not at all)	7	0
2(little)	14	1
3(moderate)	3	4
4(very)	0	13
5(exteremely)	0	6

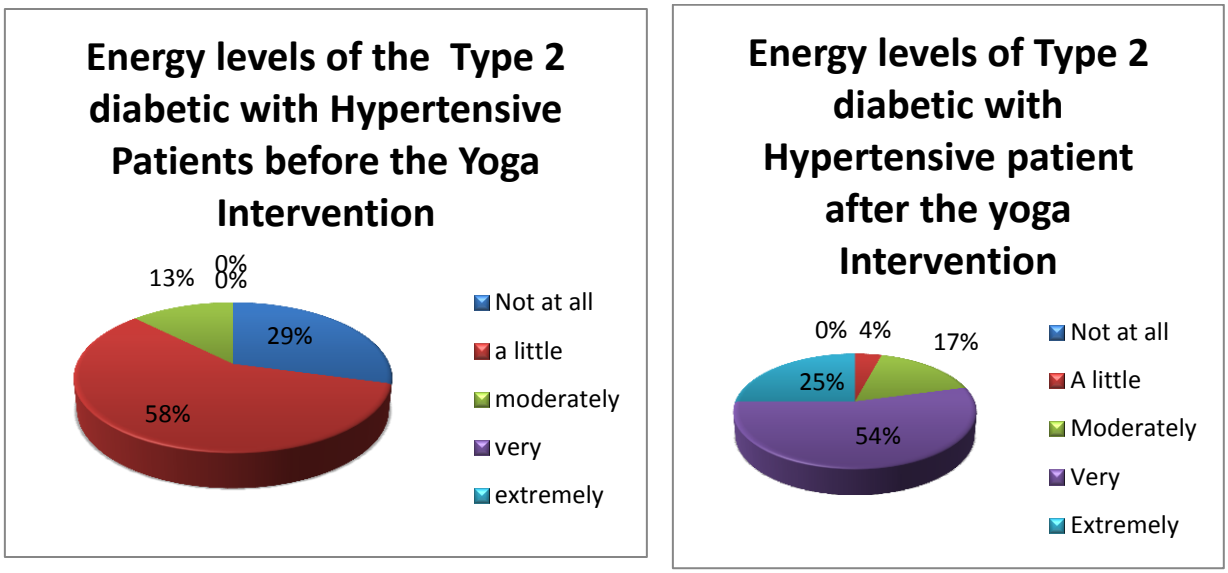


Fig: 9

B. Urination frequency:

Distribution and Variation in urination frequency of the patient before and after the 45 days of Yoga Intervention is shown in table 10 and in figure 10.

Table 10:

Assessment Rankings for urinary Frequency Levels	Number of Patietnts	
	Before(0 day)	After(45th day))
1(not at all)	0	7
2(little)	2	12
3(moderate)	6	5
4(very)	15	0
5(exteremely)	1	0

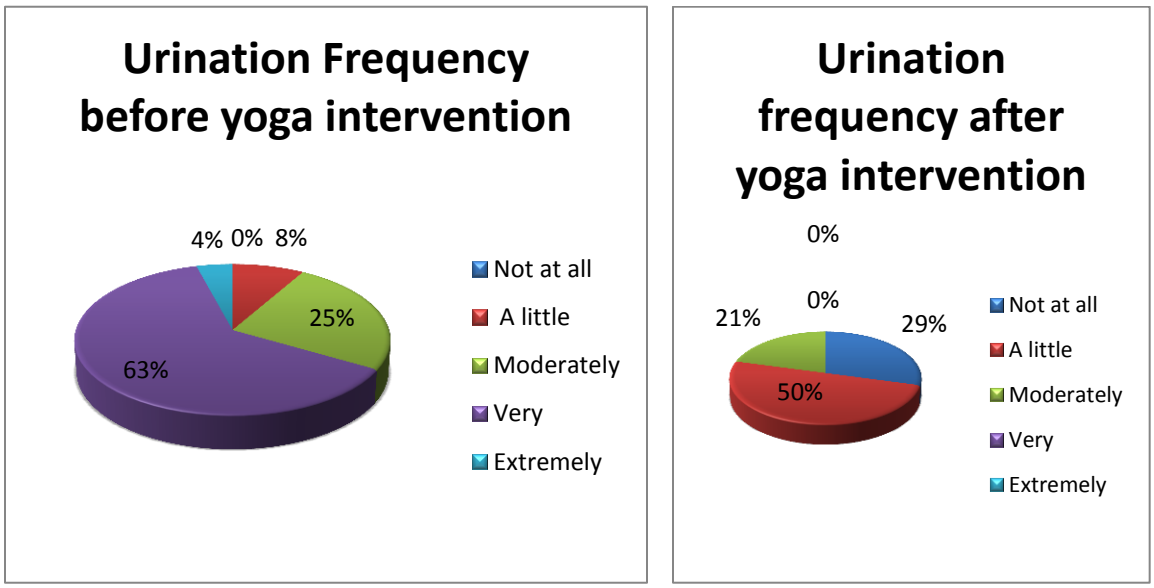


Fig: 10

C. Aching intensity in calves:

Distribution and variation of Patients according to their intensity of ache on their Calves before and after the 45 days of yoga Intervention was shown in table 11 and figure 11.

Table 11:

Assessment Rankingsfor Intensity of Aching in Calves	Number of Patietnts	
	Before(0 day)	After(45th day)
1(not at all)	4	4
2(little)	5	8
3(moderate)	4	12
4(very)	7	0
5(exteremely)	4	0

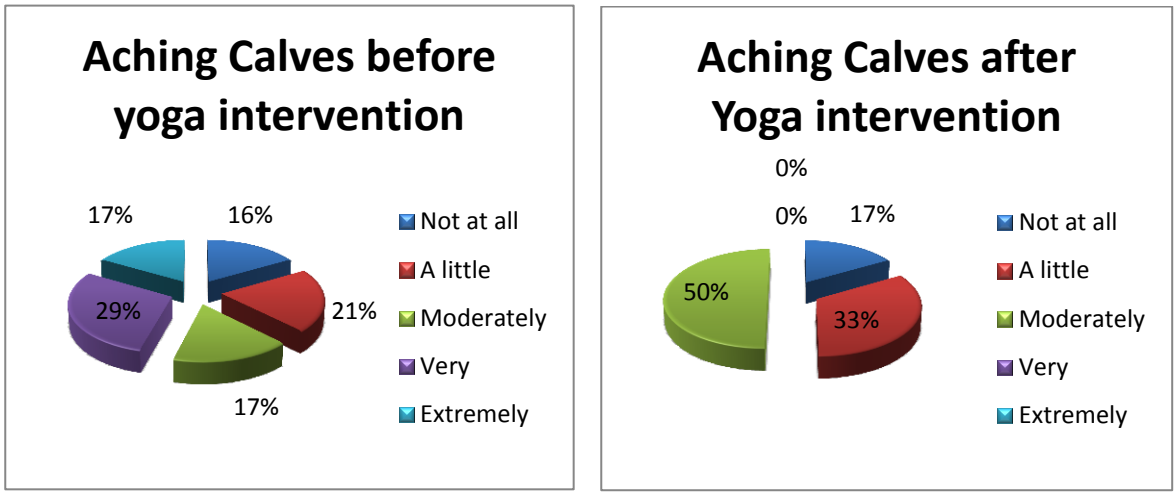


Fig: 11

D. Intensity of dry mouth :

Table 12 and figure 12 shows the distribution and variation of Patients based on their Intensity of dry mouth before and after the 45 days of yoga Intervention.

Table12:

Assessment Rankings for Intensity of Dry Mouth	Number of Patietnts	
	Before(0 day)	After(45th day)
1(not at all)	7	13
2(little)	4	9
3(moderate)	7	2
4(very)	8	0
5(exteremely)	0	0

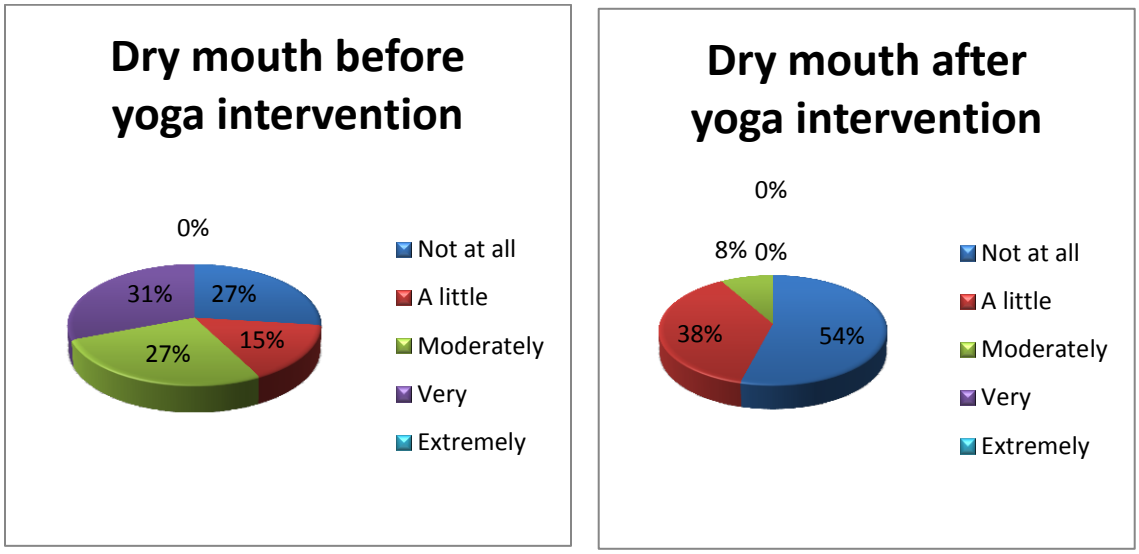


Fig: 12

F. Thirst frequency:

Distribution and variation of Patients based on the thirst frequency before and after the 45 days of yoga Intervention shown in the table13 and figure 13.

Table 13:

Assessment Rankingsfor Thirst Frequency	Number of Patients	
	Before (0 day)	After(45th day)
1(not at all)	2	7
2(little)	3	11
3(moderate)	7	6
4(very)	9	0
5(exteremely)	3	0

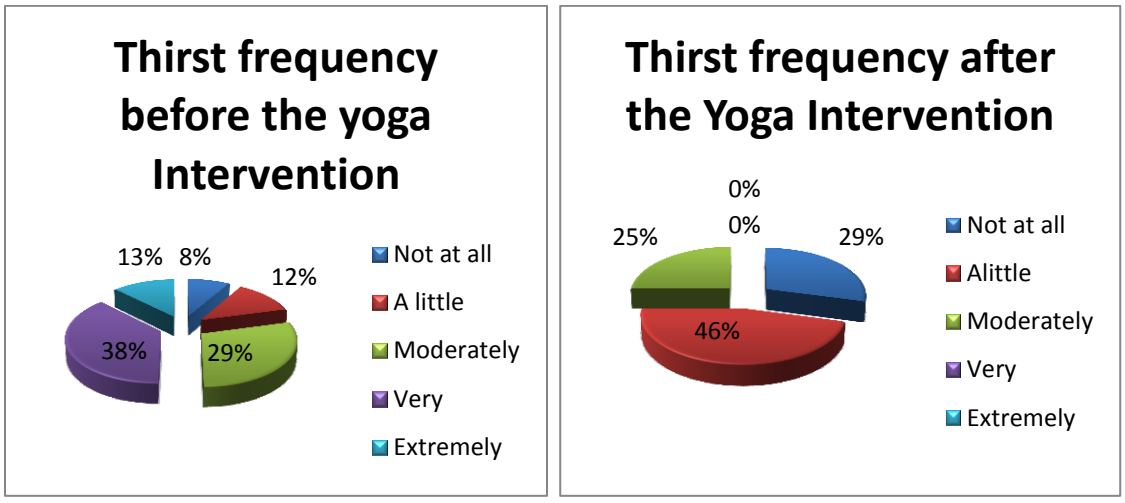


Fig: 13

E. Existence of Irritability before the meal:

Distribution and variation of Patients based on their Existance of Irritability before the meal before and after the 45 days of yoga Intervention shown in the table14 and in the figure 14.

Table 14 :

Assessment Rankingsfor Intensity of Irritability just before the Meal	Number of Patients	
	Before(0 day)	After(45th day)
1(not at all)	19	21
2(little)	0	3
3(moderate)	0	0
4(very)	4	0
5(exteremely)	1	0

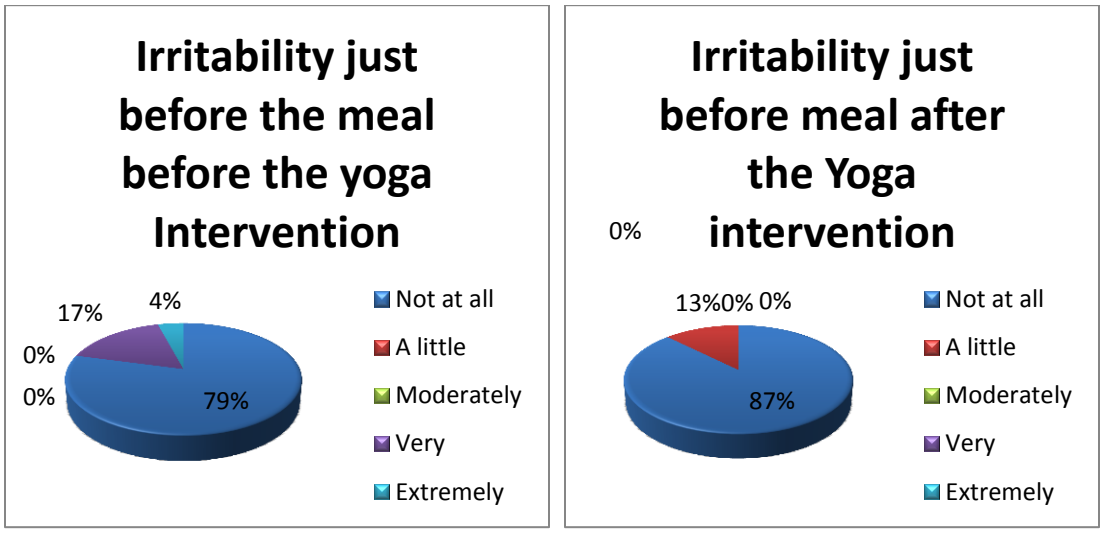


Fig: 14

G. Feeling of numbness or loss of sensation in the feet:

Distribution and variation of Patients based on their feeling of numbness before the meal before and after the 45 days of yoga Intervention shown in the table 15 and in the figure 15.

Table 15:

Assessment Rankingsfor Feeling of Numbness or Loss of Sensation in Feet	Number of Patients	
	Before (0 day)	After(45th day)
1(not at all)	7	10
2(little)	3	7
3(moderate)	6	5
4(very)	4	2
5(exteremely)	4	0

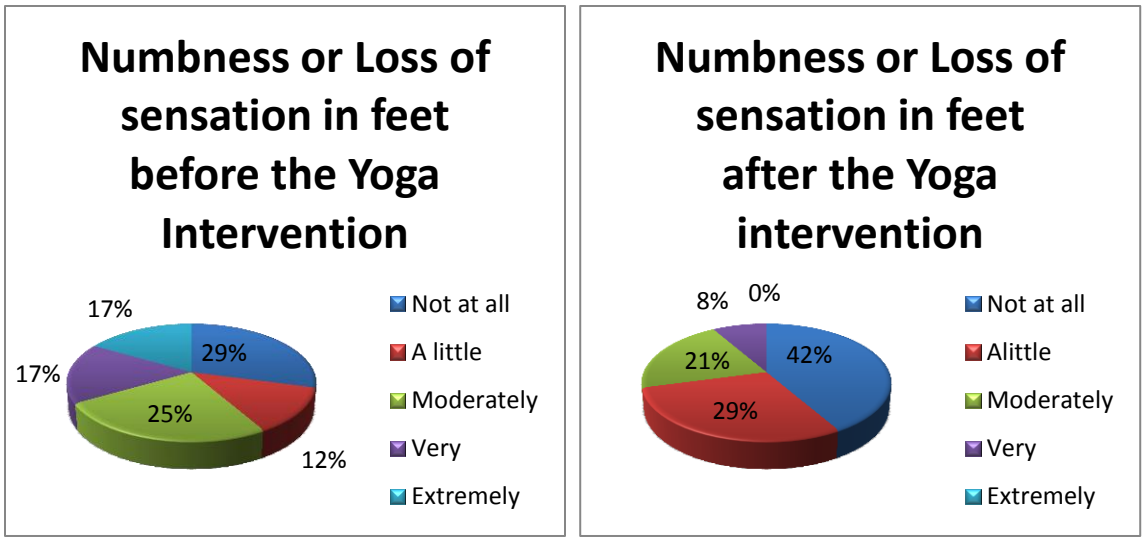


Fig: 15

H. Palpitation frequency :

Distribution and variation of Patients based on their palpitation frequency before and after the 45 days of yoga Intervention shown in the table 16 and in the figure 16.

Table 16:

Assessment Rankingsfor Palpitation Frequency	Number of Patients	
	Before(0 day)	After(45th day)
1(not at all)	11	17
2(little)	0	6
3(moderate)	7	1
4(very)	4	0
5(exteremely)	2	0

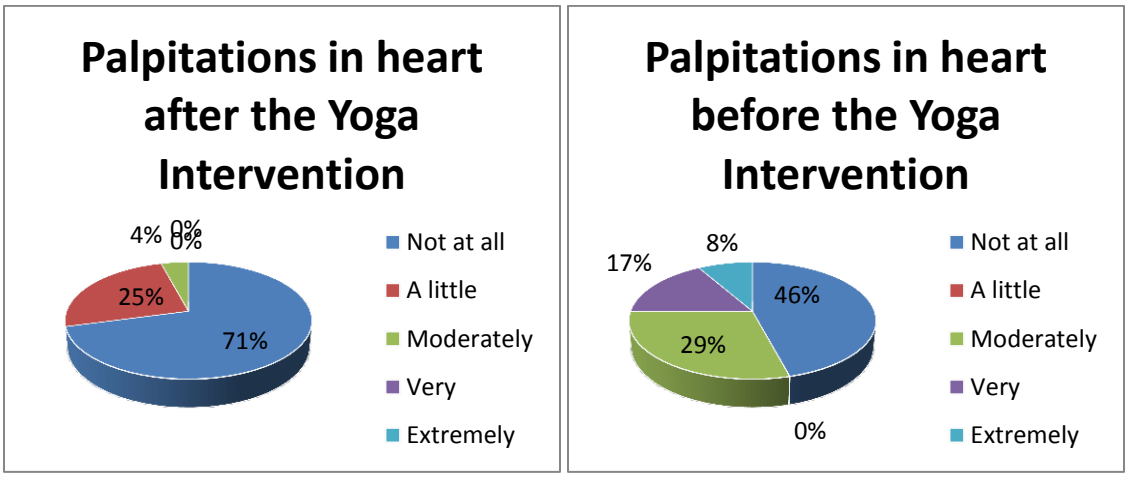


Fig: 16

I. Sense of fatigue :

Distribution and variation of Patients based on their sense of fatigue before the meal before and after the 45 days of yoga Intervention shown in the table 17 and in the figure 17.

Table 17:

Assessment Rankings for sense of Fatigue	Number of Patients	
	Before (0 day)	After(45th day)
1(not at all)	13	12
2(little)	7	4
3(moderate)	4	5
4(very)	0	3
5(exteremely)	0	0

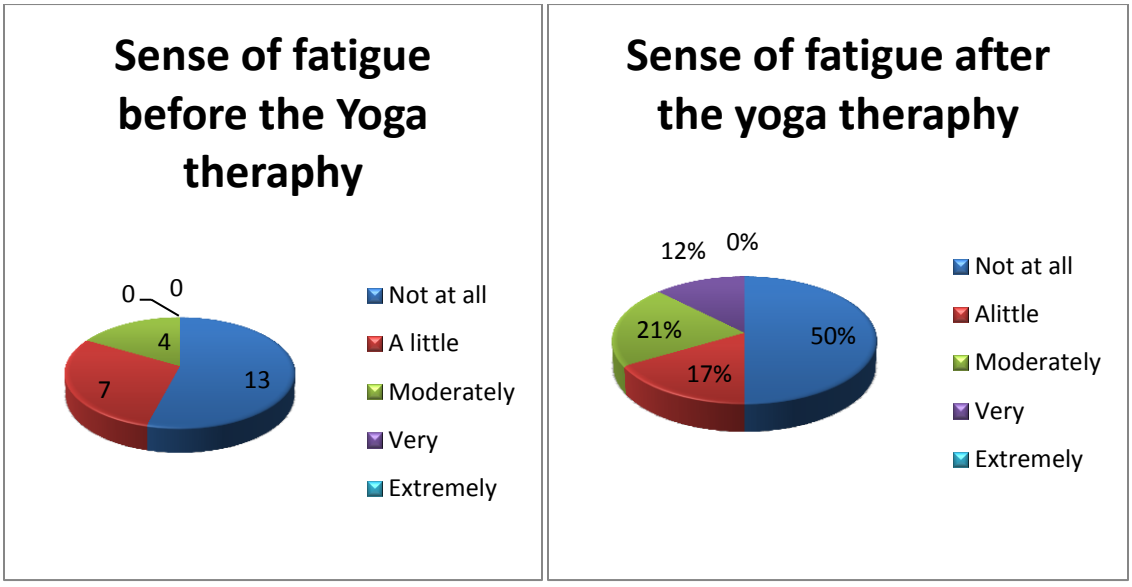


Fig: 17

The patients felt more energetic, their urination frequency, dry mouth intensity, irritability before the meal, thirst frequency, palpitations, numbness, aching in calves was efficiently reduced but sense of fatigue was found to be increased which may be due to the increased hypoglycemic states and few patients reported that they have minimized the drug doses themselves without consulting the physician but their blood glucose levels remained normal even after the withdrawal of the few doses which adds further interest in this areas.

CONCLUSION

It can be concluded from this study that Regular yoga practice is very effective in minimizing the oxidative stress and also beneficial in improving glycemic parameter and blood pressure. From the questionnaire, the patients indicated that they had reduced unpleasant side effects when they were on the yoga intervention. Yoga was not beneficial in reducing the BMI in this short-term study.

These findings suggest that yoga Intervention has therapeutic, preventative and protective effects in Patients with type 2 diabetes with hypertension by reducing the symptoms of the disease status effectively. This may have direct impact on the dose minimization of the patient which requires further study in this area.

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INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI-3

EC Reg No.ECR/270/Inst./TN/2013
Telephone No. 044 25305301 .
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
Mr. L. Gowtham
M. Pharm II Year
Madras Medical College
Chennai 600 003

Dear Mr. L. Gowtham,

The Institutional Ethics Committee has considered your request and approved your study titled " EVALUATION OF EFFECT OF YOGA THERAPY ON OXIDATIVE STRESS STATUS IN TYPE 2 DIABETIC PATIENTS WITH HYPERTENSION" **No. 41102015.**

The following members of Ethics Committee were present in the meeting held on 06.10.2015 conducted at Madras Medical College, Chennai-3.

1. Prof.C.Rajendran, M.D.,	: Chairperson
2. Prof.R.Vimala, M.D., Dean, MMC, Ch-3	:Deputy Chairperson
3. Prof.Sudha Seshayyan, M.D., Vice-Principal MMC, Ch-3	: Member Secretary
4. Prof.B.Vasanthi, M.D., Professor Pharmacology, MMC	: Member
5. Prof.P.Ragumani, M.S., Professor, Inst.of Surgery, MMC	: Member
6. Prof.Md.Ali, M.D., D.M., Prof. & HOD of Medl.G.E., MMC	: Member
7. Prof.Baby Vasumathi, Director, Inst.of O&G, Ch-8	: Member
8. Prof.K.Ramadevi, Director, Inst.of Biochemistry, MMC	: Member
9. Prof.Saraswathy, M.D., Director, Inst. Of Pathology, MMC	: Member
10. Prof.Srinivasagalu, Director, Inst.of Inter Med. MMC	: Member
11. Tmt. Rajalakshmi, Jr. Administrative Officer	: Lay Person
12. Thiru S.Govindasamy, B.A., B.L.,	: Lawyer
13. Tmt.Arnold Saulina, M.A., MSW.,	: Social Scientist

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

Member Secretary, Ethics Committee

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003

EVALUATION OF EFFECT OF YOGA THERAPY ON OXIDATIVE STRESS STATUS IN NEWLY DIAGNOSED TYPE2 DIABETIC PATIENTS WITH HYPERTENSION.

NAME: AGE/SEX : PLACE:

OP no:

DIAGNOSIS:

DETAIS OF PATIENT	FIRST VISIT	FINAL VISIT
CHIEF COMPAINTS		
PAST HISTORY		
PERSONAL HISTORY		

CLINICAL EXAMINATION:

GENERAL	AT BASE LINE	AT THE END OF 45 DAYS
Pulse		
Blood pressure		
Height		
weight		
BMI		
Blood Glucose		

INVESTIGATIONS 1:

OXIDATIVE STRESS MARKER	FIRST VISIT	LAST VISIT
MALONDIALDEHYDE		

சுய ஒப்புதல் படிவம்

ஆய்வு தலைப்பு
புதிதாக நோய் ஆய்வுறுதி செய்யப்பட்ட நீரிழிவு உடன் உயர் இரத்த அழுத்த நோயாளிகளுக்கு யோகோ முறையின் மூலம் ஆக்ஸிடேட்டிவ் ஸ்டிரஸ் (ஆக்ஸிஜனேற்ற அழுத்தம்) வேதிப்பொருள்களின் அளவில் மாற்றத்தை கண்டறிதலுக்கான ஆய்வு.

பெயர் வயது: தேதி: உள் நோயாளி எண்:

..... என்பவராகிய நான் இந்த ஆய்வின் விவரங்களும் அதன் நோக்கங்களும் முறையாக அறிந்து கொண்டேன். எனது சந்தேகங்கள் அனைத்திற்கும் தகுந்த விளக்கம் அளிக்கப்பட்டது. இந்த ஆய்வில் முழு சுதந்திரத்துடன் மற்றும் சுய நினைவுடன் பங்கு கொள்ள சம்மதிக்கிறேன்.

எனக்கு விளக்கப்பட்ட விஷயங்களை நான் நன்கு புரிந்தகொண்டு எனது சம்மதத்தைத் தெரிவிக்கிறேன். இச்சுய ஒப்புதல் படிவத்தைப் பற்றி எனக்கு விளக்கப்பட்டது.

இந்த ஆய்வினை பற்றிய அனைத்து தகவல்களும் எனக்கு தெரிவிக்கப்பட்டது. இந்த ஆய்வில் எனது உரிமை மற்றும் பங்கினைப் பற்றி அறிந்து கொண்டேன்.

இந்த ஆய்வில் பிறரின் நிர்பந்தமின்றி என் சொந்த விருப்பத்தின் பேரில்தான் பங்கு பெறுகிறேன் மற்றும் நான் இந்த ஆராய்ச்சியிலிருந்த எந்நேரமும் பின்வாங்கலாம் என்பதையும் அதனால் எந்த பாதிப்பும் ஏற்படாது என்பதையும் நான் புரிந்து கொண்டேன்.

இந்த ஆய்வில் கலந்து கொள்வதன் மூலம் என்னிடம் பெறப்படும் தகவலை ஆய்வாளர் இன்ஸ்டிட்யூசனல் எத்திக்ஸ் கமிட்டியினரிடமோ, அரசு நிறுவனத்தினடமோ தேவைப்பட்டால் பகிர்ந்து கொள்ளலாம் என சம்மதிக்கிறேன்.

இந்த ஆய்வின் முடிவுகளை வெளியிடும்போதே எனது பெயரோ, அடையாளமோ வெளியிடப்படாது என அறிந்து கொண்டேன். இந்த ஆய்வின் விவரங்களைக் கொண்ட தகவல் தாளைப் பெற்றுக் கொண்டேன். இந்த ஆய்விற்காக இரத்தப் பரிசோதனை செய்து கொள்ள சம்மதிக்கிறேன்.

இந்த ஆய்வில் பங்கேற்கும் பொழுது ஏதேனும் சந்தேகம் ஏற்பட்டால், உடனே ஆய்வாளரை தொடர்பு கொள்ள வேண்டும் என அறிந்து கொண்டேன்.

இச்சுய ஒப்புதல் படிவத்தில் கையெழுத்திடுவதன் மூலம் இதிலுள்ள அனைதது விஷயங்களும் எனக்கு தெளிவாக விளக்கப்பட்டது என்று தெரிவிக்கறேன். இச்சுய ஒப்புதல் படிவத்தின் ஒரு நகல் எனக்கு கொடுக்கப்படும் என்றும் தெரிந்து கொண்டேன்.

ஆய்வாளர் கையொப்பம்

தேதி

பங்கேற்பாளர் / பாதுகாவலா
கையொப்பம்

ஆய்வு தகவல் தாள்

ஆய்வு தலைப்பு

புதிதாக நோய் ஆய்வுறுதி செய்யப்பட்ட நீரிழிவு உடன் உயர் இரத்த அழுத்த நோயாளிகளுக்கு யோகோ முறையின் மூலம் ஆக்ஸிடேட்டிவ் ஸ்டிரஸ் (ஆக்ஸிஜனேற்ற அழுத்தம்) வேதிப்பொருள்களின் அளவில் மாற்றத்தை கண்டறிதலுக்கான ஆய்வு.

ஆய்வாளர் :
பங்கேற்பாளர் :

இந்த ஆய்வு இராஜீவ் காந்தி அரசு பொது மருத்துவமனையில் நடைபெற உள்ளது. நீங்களும் இந்த ஆய்வில் பங்கேற்க நாங்கள் விரும்புகிறோம். இதிலுள்ள தகவலின் அடிப்படையில் இந்த ஆய்வில் பங்கேற்பதா அல்லது வேண்டாமா என்று நீங்கள் முடிவுசெய்துகொள்ளலாம். உங்களது சந்தேகங்களை எங்களிடம் கேட்டு நிவர்த்தி செய்துகொள்ளுங்கள்.

இந்த ஆய்வின் நோக்கம்

ஆக்ஸிஜனேற்ற அழுத்தம் நீரிழிவு நோய் உடன் உயர் இரத்த அழுத்தம் தோன்ற ஒரு முக்கிய பங்கு வகிக்கிறது. இந்திய பண்டைய முன்னோர்களின் கலைப்பண்பார்ந்த இலக்கிய படைப்பின்படி யோகா முறையானது நீரிழிவு உடன் உயர் இரத்த அழுத்தம் உடையவர்களுக்கு ஆக்ஸிஜனேற்ற அழுத்தத்தை குறைப்பதில் சிறந்த பங்கு வகிப்பதாக கூறப்பட்டுள்ளது. மேலும் யோகா பயிற்சியானது வழக்கமாக எடுத்துக்கொள்ளும் சிகிச்சை முறையுடன் சேர்த்து கொடுத்து சோதிக்க உள்ளோம்.

இந்த ஆய்விற்கு இன்ஸ்டிட்யூசனல் எத்திக்ஸ் கமிட்டி சம்மதம் பெற்றிருக்கிறோம்.

ஆய்வின் வடிவமைப்பு

யோகா முறையில் தன்னார்வமுள்ள நீரிழிவு உடனான உயர் இரத்த அழுத்த நோயாளிகளுக்கு 90 நாட்கள் யோகா முறை பயிற்சி அளித்து ஆக்ஸிஜனேற்ற அழுத்தத்தின் வேதிப்பொருட்களின் அளவை யோகா பயிற்சியின் முன்பும் பின்பும் ஒப்பிட்டுப்பார்க்க உள்ளோம்.

ஆய்வு நடைமுறைகள்

இந்த ஆய்வில் இரத்த அழுத்தம், இரத்த சர்க்கரை அளவு, உடல் பருமன் எடை மற்றும் ஆக்ஸிஜனேற்ற அழுத்தத்தின் வேதிப்பொருட்களின் அளவு ஆகியவை மதிப்பீடு செய்யப்படும்.

ஆய்வின் தொடக்கத்தில் தங்களிடமிருந்து 5 மி.லி. அளவு இரத்தம் எடுக்கப்படும்.

இந்த ஆய்வில் 90 நாட்கள் தங்களுக்கு யோகா பயிற்சி அளிக்கப்பட்டு 90 நாட்களுக்கு பிறகு தங்களிடமிருந்து 5 மி.லி. அளவு இரத்தம் பரிசோதனைக்காக எடுக்கப்படும்.

இப்பரிசோதனையில் இருமுறை தங்களிடமிருந்து பெற்ற இரத்தத்தில் உள்ள ஆக்சிஜனேற்ற அழுத்தத்திற்கான வேதிப்பொருட்களின் அளவை ஒப்பிட்டு அதன்மூலம் நோயின் தன்மையில் ஏற்படும் முன்னேற்றத்தை அறிந்துகொள்ளலாம்.

ஆய்வினால் ஏற்படும் நன்மைகள்

தங்களின் வழக்கமான மருந்துகளுடன் இணைந்து யோகா பயிற்சி அளிப்பதன் மூலம் ஆக்சிஜனேற்றம் குறைவது மட்டுமின்றி இந்த யோகா பயிற்சியினை தங்களது அன்றாட வாழ்விற்கு உதவுவதுடன் உங்களின் நோய் குணமடைவதில் சிறந்த முன்னேற்றம் ஏற்படும். ஆய்வின் முடிவுகள் எதிர்காலத்தில் இந்நோய்குறி உள்ளவர்களுக்கான சிகிச்சை முறையிலும் மற்றும் மருத்துவ அறிவிலும் முன்னேற்றம் ஏற்பட்டு சமூகத்திற்கு நன்மைகளை வழங்கலாம்.

உங்களிடமிருந்து பெறப்பட்ட தகவலின் நம்பகத்தன்மை

தங்களது மருத்துவ சிகிச்சை குறித்த தகவல்கள் இரகசியமாக பாதுகாக்கப்படும். இந்த தகவல் தாளில் கையெழுத்திடுவதின் மூலம் உங்களை பற்றிய குறிப்புகலோ, எடுத்துக்கொண்ட சிகிச்சை முறையை பற்றியோ ஆய்வாளரோ, இன்ஸ்டிட்யூசனல் எத்திக்ஸ் கமிட்டியை சார்ந்தவர்களோ தேவை ஏற்பட்டால் அறிந்து கொள்ளலாம் என்று சம்மதிக்கிறீர்கள். ஆய்வின் போதோ அல்லது முடிவுகளை வெளியிடும்போதோ தங்களது பெயரையோ, அடையாளங்களையோ வெளியிடமாட்டோம் என்பதை தெரிவித்துக்கொள்கிறோம்.

இந்த ஆய்வில் பங்கேற்காவிட்டாலும் நீங்கள் வழக்கமான சிகிச்சையை தொடர்ந்து பெறலாம்.

இந்த ஆய்வில் பங்கேற்பது தங்களுடைய விருப்பத்தின் பேரில்தான் இருக்கிறது. மேலும் நீங்கள் எந்நேரமும் இந்த ஆய்விலிருந்து பின்வாங்கலாம் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

இந்த சிறப்பு சிகிச்சையின் முடிவுகளை ஆய்வின்போதோ அல்லது ஆய்வின் முடிவின் போதோ தங்களுக்கு அறிவிப்போம் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

ஆய்வாளர் கையொப்பம்

பங்கேற்பாளர் / பாதுகாவலர் கையொப்பம்

தேதி

SAVEETHA MEDICAL COLLEGE

Department of Pharmacology

CERTIFICATE

This is to certify that ~~Dr~~ / Mr / ~~Ms~~ / ~~Mrs~~ L.GOWTHAM,

has Participated as Delegate / ~~Guest speaker~~ / ~~Chairperson~~ / Presented ~~Oral / Poster~~ and Presentation Titled

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in the **"Challenges in Drug Development", a State Level Pharmacology Conference**

held on 21st June 2014, carrying Two credit points accredited by Tamilnadu Medical Council TNMC.

Organising Secretary
Department of Pharmacology, SMC

DEAN
Saveetha Medical College

66th Indian Pharmaceutical Congress Hyderabad

66th INDIAN PHARMACEUTICAL CONGRESS

23rd TO 25th, JANUARY 2015, HITEX, HYDERABAD.

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HAS PARTICIPATED AS DELEGATE

IN 66th INDIAN PHARMACEUTICAL CONGRESS

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INTRODUCTION

REVIEW OF LITERATURE

AIM AND OBJECTIVES

METHODOLOGY

RESULTS AND DISCUSSION

CONCLUSION

BIBLIOGRAPHY

ANNEXURE

PLAN OF WORK